

State and Local Area Integrated Telephone Survey
OMB # 0920-0406

Supporting Statement A

Three-year generic clearance granted 04/25/11
Expires 04/30/14

GenIC request to add additional topics:
National Survey of the Diagnosis and Treatment of ADHD
and Tourette Syndrome (NS-DATA)

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October 31, 2013

The State and Local Area Integrated Telephone Survey (SLAITS)
OMB clearance number 0920-0406
Expiration 04/30/14

**GenIC: National Survey of the Diagnosis and Treatment
of ADHD and Tourette Syndrome (NS-DATA)**

OVERVIEW

The State and Local Area Integrated Telephone Survey (SLAITS) mechanism is conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), under OMB generic clearance number 0920-0406 (expires 04/30/14). This three-year clearance allows NCHS to collect health and well-being data on children, families, and communities. The SLAITS mechanism by definition is integrated with the National Immunization Survey (Paperwork Reduction Act (PRA) exempt). NCHS is applying for clearance to add a topic module genIC to the SLAITS National Survey of Children's Health (NSCH) as a follow-back interview survey. This 2014 follow up is referred to in this information collection request package as the National Survey of the Diagnosis and Treatment of ADHD and Tourette Syndrome (NS-DATA). The NS-DATA module is a collaboration between CDC's NCHS and the National Center on Birth Defects and Developmental Disabilities (NCBDDD).

The subgroup of NSCH children that the NS-DATA will follow back in this module are those who were ever diagnosed with Attention Deficit/Hyperactivity Disorder (ADHD) or Tourette Syndrome (TS). All children eligible for the NS-DATA module were the subjects of completed interviews in the 2011-2012 NSCH. The NS-DATA is intended to supplement the data collected during the NSCH for these children.

The NS-DATA is scheduled to be in the field from January through April 2014.

A. Justification

1. Circumstances Making the Collection of Information Necessary

2014 Follow up of a NSCH subpopulation: National Survey of the Diagnosis and Treatment of Attention-Deficit/Hyperactivity and Tourette Syndrome (NS-DATA)

The NS-DATA is focused on a small subgroup of children identified in the large-scale 2011-2012 NSCH, which was conducted under the SLAITS mechanism. The NS-DATA is intended to follow back to children ever diagnosed with ADHD or TS who were identified as such during

the administration of the 2011-2012 NSCH. The survey content has focused on providing data to address two main objectives: describing the characteristics of the population and describing the level of access and utilization of various services, including pathways to diagnosis and treatment for the child and their family. Of 6,360 children ever diagnosed with ADHD, TS or both at original interview and projected to still be under age 18 at re-interview, approximately 3,700 completed NS-DATA interviews are expected. We anticipate the final sample will include approximately 3,600 children who have been diagnosed with ADHD, 50 children who have been diagnosed with TS, and 50 children who have been diagnosed with both TS and ADHD. The interview for children with either ADHD or TS will be approximately 30 minutes in length. For children with both conditions the interview will last approximately 50 minutes.

The NS-DATA is sponsored by CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD). The NS-DATA addresses NCBDDD's organizational dedication to promoting research on the causes, diagnosis, early detection, prevention, control, and treatment of developmental disorders. ADHD and TS are related neurodevelopmental disorders of considerable interest to NCBDDD. The proposed research is also consistent with the CDC mission to promote health and quality of life by preventing and controlling disease, injury, and disability by a variety of means, including conducting research to enhance prevention.

Detailed nationally representative population-based data on service and treatment utilization on families raising a child with ADHD are limited. A better understanding for the diagnosis and treatment of ADHD may lead to conclusions of relevance for the fields of medicine and public health and may be particularly important given newly released clinical diagnosis and treatment guidelines for ADHD. Specifically, research that assesses the alignment of current diagnostic and treatment practices with professional guidelines may inform public health approaches to improved clinical management of children with ADHD. What is needed is a population-based, nationally representative survey of children with ADHD in which the particular difficulties facing this population are assessed. The SLAITS mechanism provides a platform to identify a cross-sectional sample of such families, and will allow for the unique opportunity to study the relationship of diagnostic and treatment factors and functional health status among a nationally-representative sample of children diagnosed with ADHD.

The NS-DATA also takes advantage of the fact that the NIS and NSCH screen a large number of households to obtain a large probability sample of children in rare populations, such as children ever diagnosed with TS. It should be noted however that the sample of children with TS is unlikely to be nationally representative, due to the small expected sample size.

The 2011-2012 NSCH sample represents all non-institutionalized children ages 0-17 in the United States. The NS-DATA takes advantage of the fact that the 2011-2012 NSCH screened a large number of households to identify a population of children diagnosed with either ADHD or TS. Caregivers of children ages two to 17 years, identified in the NSCH as having children with ADHD or TS, will be interviewed (those otherwise-eligible children who have aged to age 18 between interviews will be out of scope).

The NS-DATA dataset will be unique for a variety of reasons: (1) it will be the only nationally representative survey that provides a comprehensive understanding of the diagnostic and

treatment process utilizing a cross-sectional profile of children diagnosed with ADHD; (2) the NS-DATA will benefit from the large quantity of health and well-being data that have already been collected on these children in the NSCH; and (3) the NS-DATA data will be collected at a later time (2-3 years) than the original NSCH data collection, allowing for the examination of changes over time in such critical variables as household income, health insurance coverage, and family structure stability.

In short, given the magnitude of public concern over the diagnosis and treatment of ADHD, these data are particularly necessary for public health planning. Additionally, these data will substantially increase the knowledge about ADHD and TS in non-clinical populations and may result in the enhanced quality of life for these individuals. The knowledge gained from this study will assist the CDC, in providing the public and health professionals with the most accurate and up-to-date information concerning ADHD and TS. Moreover, most of what is known about TS is limited to clinic-based samples. NS-DATA will represent the only probability sample of children ever diagnosed with TS that we know of. Without these data, the CDC would be limited in its ability to make the most informed decisions and recommendations concerning treatment, prevention of secondary conditions or risk behaviors, and health care service experience of individuals with ADHD and TS.

Law and regulation that authorizes this data collection:

NCHS is authorized to collect data under Section 306 of the Public Health Service Act (42 USC 242k). Text from this section of the code was submitted in the three-year generic clearance package and is not included here.

New data elements:

Most variables to be asked in the NS-DATA follow-back interview are questions not previously asked about these NSCH children. The goal is not to re-assess information already collected but rather to supplement the original data collection with additional information. That said, however, there are some exceptions. Classification information, such as household income and current insurance status, will be re-asked to ensure accuracy. The rest of the NS-DATA questions are expansions of data elements already collected in the NSCH. For the most part, new data elements are intended to capture more detail about the child's medical and diagnostic history, including access to health care and related services, health related behaviors, as well as an evaluation of the child's current social and behavioral functioning. There are a few questions that are truly new and not expansions of NSCH questions, because they would not have been relevant to the vast majority of NSCH subjects, such as child's adherence to medication, and questions focused on the presence of TS.

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The Computer Assisted Telephone Interview (CATI) system will be designed with a core set of questions applicable to all eligible children. Subsequent questions will depend on whether the child had ADHS, TS or both. Sections of the instrument include diagnosis history, treatment history, presence of co-occurring conditions, current functioning, and academic functioning. Data elements from the NS-DATA instrument (Attachment A) that have not been collected before in previous SLAITS modules are listed below.

New SLAITS data elements that are common for all NS-DATA children include:

- Have other family members been diagnosed with ADHD
- What level of involvement did you/[parents] have in the ADHD diagnostic evaluation
- What are side effects your child may have experienced from their medication
- When did your child start taking medication
- How often does your child take medication for their ADHD
- Was it difficult to get your child to take their medication
- Has your child's medication ever been taken or used by someone else

Cases in which the child has been diagnosed with Tourette Syndrome will be asked:

- Has your child been treated differently because of his/her tics
- Do certain things make your child's tics worse
- Has your child ever received comprehensive behavioral intervention for tics (CBIT) or habit reversal therapy
- Do you believe anything in particular caused your child to start having tics

In addition, six new questions on disability and one new question on language proficiency were added to comply with DHHS Data Collection Standards required for all DHHS surveys (see <http://aspe.hhs.gov/datacncl/standards/ACA/4302/index.shtml>).

Privacy Impact Assessment Information

Overview of the data collection system:

The respondent will be an adult parent or guardian who lives in the household and is knowledgeable about the health and health care of the sampled child. Data will be collected by telephone using trained interviewers from a centralized telephone center. The telephone center site will use standardized data collection and training methods. Telephone numbers will be dialed with either an automatic dialer (for landline numbers) or by hand for cellular telephone sample to comply with the Telephone Consumer Protection Act (TCPA). Once a call is placed, the recipient's Caller ID unit usually registers the contractor's name unless local companies truncate or change the display, an operation they control.

The contractor will conduct all sample management and data collection, and maintain NSCH data and sampled case information until the project ends. Confidential data will be stripped from the survey data and will be maintained by NCHS on a server equipped with firewalls and access limited to two key people. Through its website, NCHS will release one public use file (PUF) that does not contain identifiable information. Following review by an internal nondisclosure committee, the public use file will be available for use indefinitely at no charge. Data not available on the public use file due to disclosure risk may be available to researchers through the NCHS Research Data Center.

Information in Identifiable Form

The information in identifiable form (IIF) needed for this survey, with the exception of new contact information for previous respondents who have since moved, has been previously collected through the 2011-2012 NSCH. Previously collected information will mainly be used to re-contact and verify eligible respondents. Although the vast majority of data collected are not considered personally identifiable, some fit the definition of IIF and are listed below. We may

explore data linkage in this survey, but this information would not be released in the PUF. The only data from the list below that will be released to the public or become part of the public use files is age of the eligible child and year of birth of their caregiver(s), which may be perturbed if necessary to maintain confidentiality. None of the other IIF data will be released to the public or become part of public-use files.

The IIF are collected by the contractor, and once separated from interview data, the file is transmitted to the CDC using a secure data network. These data are not accessible to anyone other than the NCHS Project Director and the project's computer scientist.

IIF items:

- name or initials of the respondent
- first name or initials of the sampled child
- another telephone number where the respondent can be reached if the sampled telephone number is not working for any reason;
- additional telephone number type (e.g., cellular, landline, or work number)
- mailing address with zip code obtained through a telephone and address matching procedure (or directly from some respondents)
- zip code collected directly from the respondent
- state name of the state the respondent lives in
- age in months or years for children in the household
- date of birth in whole years for the eligible child's parent(s) or guardian(s)

These IIF are obtained for several reasons.

- Both the telephones and addresses are used to re-contact households that are eligible for this survey. Telephone numbers are linked to addresses whenever possible so that an advance letter (Attachment B) can be sent to the households prior to being called for an interview. The phone number and address are on a Record of Calls file which is separate from the interview file, and is never released to the public. Also, the monetary incentive is sent via first class mail. The address information is either confirmed from the earlier matching activity or obtained from households if the only known information is the telephone number. All mailed letters can be found in Attachment B.
- The child's first name or initials are collected to identify the person to whom the questions refer. To reduce the respondent's cognitive burden and make questionnaire administration less awkward (e.g., by not having to repeatedly ask about the "X-year old child", the child's first name or initials may be substituted in the computerized interviewing system.
- The respondent's first name or initials and relationship to the child are used to identify the person who originally participated in the 2011-2012 NSCH.
- The eligible child's age is collected to identify the eligible child selected for this survey, for weighting adjustments, and for analytic purposes. Again, the child's age may be perturbed before releasing the PUF if necessary.

Identification of website(s) and website content directed at children under 13 years of age:

There is no web-based data collection. The advance letter used for this survey states "You may visit <http://www.cdc.gov/nchs/slaits.htm> to find general information about the study".

Absolutely no content and information on these websites or subpages is directed at children under the age of thirteen years. No children are interviewed in this survey.

2. Purpose and Use of Information Collection

This survey meets specific programmatic needs of NCBDDD as described above in section A.1. NCBDDD's stated mission is to:

Promote the health of babies, children and adults and enhance the potential for full, productive living. NCBDDD works to identify the causes of birth defects and developmental disabilities, help children to develop and reach their full potential, and promote health and well-being among people of all ages with disabilities.

In order to provide a comprehensive picture of children with ADHD and TS and the families caring for them, descriptive analyses will be conducted using all NS-DATA characteristic data elements, as well as selected variables from the NSCH. It is important to generate a thorough description of these children and families using data from NS-DATA and NSCH. Currently, no other federal data source can be used to provide a rich description of the population.

NCBDDD and NCHS anticipate a variety of analyses, specifics of which will be determined by preliminary analysis, and disseminated in research briefs, NCHS National Health Statistics Reports, research articles to be submitted to scientific journals, or presentations at scientific conferences. One way to assess data use and utility is to examine how often the data are expected to be used in peer-reviewed publications. A partial list of selected references that describe analyses conducted by NCHS, NCDBBB, and academic researchers of previous NCHS surveys dedicated to developmental disorders is provided in Attachment C. Similar analyses are planned for the NS-DATA and will be enhanced by linked data from the initial NSCH interview. All publications and presentations completed by CDC are reviewed for technical approach and edited for content form.

Privacy Impact Assessment Information

The NS-DATA microdata file can be used to examine national-level estimates only. For this survey, in addition to baseline analyses of the data collected about the characteristics of the population, child and parent well-being, and access and utilization of services, we will also be able to link the NS-DATA data to their NSCH responses to analyze the health, health care access and use and health insurance of children with ADHD and TS. Disclosure risk analysis will determine whether the linked NSCH- NS-DATA data file will be released to the public; if it cannot be released, the NS-DATA file will be released in such a way that the linkage between the files cannot be accomplished using the public files alone. Data perturbation and suppression will be employed as necessary to ensure that all cases are protected from disclosure.

- A. This study is covered under Privacy Act System of Records Notice 09-20-0164 ("Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population").

- B. NCHS collects only names, addresses, and telephone numbers, for screening, verification, and for mailing incentives. They are stored encrypted, and separately from the survey data and are not released publically. Social Security numbers are not collected.
- C. The confidentiality of individuals participating in SLAITS surveys is protected by section 308(d) of the Public Health Service Act (42 USC 242m), and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002, both of which are explained in Section A.10.
- D. All contractor employees who will handle confidential data are required to take the NSCH Confidentiality Training module and sign non-disclosure forms. SLAITS is an ongoing data collection effort and all appropriate contractor employee signatures are current and in effect.
- E. NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees involved in SLAITS must sign. The contractor provides all safeguards mandated by Privacy Act and Confidentiality legislation to protect the confidentiality of the data.
- F. The contractor's data security procedures comply fully with security requirements delineated by the Office of the Chief Information Security Officer (OCISO) of CDC. SLAITS has undergone Certification and Accreditation and has been granted Authority to Operate.
- G. The NCHS Research Ethics Review Board approved the continuation of the NSCH protocols on 1/14/2013 as NCHS Protocol Number 2011-05 (attachment G).

3. Use of improved information technology and burden reduction

The survey will be conducted using a CATI program in centralized telephone centers, which reduces the time required to collect, transfer, process, and release data. The CATI system also tracks all landline and cellular call outcomes and date, time of day, and length of each call, in addition to detailed notes maintained by the interviewers. It also ensures that skip patterns are followed properly. Teletype machine (TTY) administration is available to interview deaf respondents. Use of the CATI system typically reduces the average duration of interviews, compared to a paper questionnaire with identical content, thus reducing the respondent's burden. There are no technical or legal obstacles to burden reduction.

4. Efforts to identify duplication and use of similar information

To the best of our knowledge, this is the only population-based survey of children with ADHD within the Federal government, designed specifically to produce national estimates from parent interviews that focus on the diagnosis and treatment of ADHD. Although other Federal and non-Federal surveys collect health data on children (such as the National Health Interview Survey, OMB 0920-0214), none focus exclusively on relevant clinical management of children diagnosed with ADHD and TS. Moreover, although previous surveys have been large enough to include an adequate sample of children with ADHD for a reliable analysis, these surveys do not contain detailed questions that are specific to these populations. To the extent that there is some overlap in content of this module with other surveys, it is necessary to ensure that the full range of relevant variables are included for complex analyses of data for the NS-DATA sample.

5. Impact on small businesses or other small entities

No small businesses will be involved in this data collection. This is a household population-based survey.

6. Consequences of collecting the information less frequently

This is a one-time data collection.

7. Special circumstances related to the guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In compliance with 5 CFR 1320.8(d), a 30-day Federal Register notice was published in the *Federal Register* in conjunction with this GenIC request on November 1, 2013, Volume 78, number 212, page 65654 (OMB project number 0920-0406 State and Local Area Integrated Telephone Survey (SLAITS) (The National Survey of the Diagnosis and Treatment of Attention Deficit/Hyperactivity Disorder and Tourette Syndrome) (NS-DATA)(Attachment F). One public comment was received (Attachment F). The NS-DATA instrument was developed by an expert panel convened by NCBDDD. Subject matter experts consulted are listed in Attachment D. The NCBDDD staff gathered existing instruments and research materials for several large national mental health studies and examined topics which were covered or omitted in these instruments, and constructed the instrument by including questions that have been used on past surveys and crafting new questions to cover topics not previously addressed. Following an initial meeting, panel members were given the opportunity to review interim questionnaire drafts. NCBDDD and NCHS staff reviewed draft questions, suggested new topics for inclusion and sources of questions, and provided overall subject matter supervision throughout the questionnaire and survey design process.

Susanna Visser, the NS-DATA Project Officer for NCBDDD, has reviewed and approved the survey instrument and protocols for recruiting sample cases.

9. Explanation of Any Payment or Gift to Respondents

One method for reducing nonresponse is to offer respondents a monetary token of appreciation for their participation. Monetary incentives will be offered for the NS-DATA data collection.

During the initial quarters of data collection on the 2011 – 2012 NSCH, an extensive incentive experiment was undertaken exploring a variety of incentive approaches. The results of this experiment demonstrated that incorporating an incentive can indeed improve survey response rates. The most effective approaches combined a promised incentive with a further prepaid refusal-based incentive. Based on this experience, we will offer all NS-DATA eligible cases previously diagnosed with ADHD or TS an incentive of \$20 as a promised incentive for the telephone interview (averaging 30 minutes). Given that the NS-DATA eligible cases who were previously diagnosed with both ADHD and TS will require a longer interview (averaging 50 minutes), these cases will be offered a \$40 promised incentive for the longer interview. For all households that initially refuse participation, we will offer a further \$5 to be mailed to respondents as a prepaid incentive and accompanied by a tailored refusal conversion letter reiterating the purpose and importance of the NS-DATA (the refusal conversion letter is included in Attachment B). If the respondent decides to participate, \$20 (or \$40 for TS and ADHD cases) will be sent with a thank you letter, also included in Attachment B. This is similar to the incentive model employed to successfully increase response rates for two previous follow-up surveys conducted by SLAITS –the National Survey of Adoptive Parents of Children with Special Health Care Needs (NSAP-SN) and the National Survey of Children in Nonparental Care (NSCNC). These surveys, like the NS-DATA, involved conducting a follow-up survey with respondents after their eligibility was determined through the administration of a parent survey. The interview completion rates that were obtained for these follow-up surveys are in line with those expected for the NS-DATA project. The interview completion rate for NSAP-SN – which was a follow-back 1-2 years after the 2005-2006 National Survey of Children with Special Health Care Needs (NS-CSHCN) – was 65%, while the NSCNC completion rate was approximately 45%, although this survey interviewed households where locating cases was more challenging given the transient nature of the living arrangements of children in non-parental care. Therefore, an interview completion rate for a 2-3 year follow-back survey is expected to be between 55-60%.

The contractor trains especially adept interviewers to be refusal converters in its CATI center. The refusal converters not only have a prior track record for success in gaining cooperation, but also receive additional training regarding ways in which to handle hostile and unwilling respondents in a non-coercive manner. These refusal converters call households that refused participation during the initial contact. Refusal converters respond to respondents' concerns, ask if they have any questions about the study, and ask if they would like information mailed to them (e.g., a copy of the advance letter). If respondents refuse again, no further contacts are made.

10. Assurance of Confidentiality Provided to Respondents

Interviewers, supervisors, and project staff receive thorough training on legal and ethical obligations. All employees sign an Affidavit of Nondisclosure as a condition of employment.

Standards for the surveys performed for the Federal government highlight the importance of the interviewers' responsibilities under the Privacy Act of 1974 (5 U.S.C. 552a), the Privacy Act Regulations (34 CFR Part 5b), Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, Section 513 of PL 107-347), HIPAA (for the NIS), and other regulations.

An assurance of confidentiality is provided to all respondents according to section 308(d) of the Public Health Service Act (42 USC 242m) which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both."

In addition to the NCHS Research Ethics Review Board (ERB) review, survey procedures and instruments will be reviewed by the contractor Institutional Review Board (IRB) prior to fielding.

Privacy Impact Assessment Information

Confidential data will never be released to the public. For example, all personal information that could be potentially identifiable (including participant name, address, and telephone number), are removed from the public release files. The NCHS Disclosure Review Board reviews all files, including those of SLAITS, to assure that directly or indirectly identifiable data are not included.

Thus, when NCHS releases public use data files as part of its mission to disseminate the data widely, any information that could be identifiable is removed.

- A. This submission has been reviewed by the NCHS Privacy Act Officer and the NCHS Confidentiality Officer who determined that the Privacy Act does apply. This study is covered under Privacy Act System of Records Notice 09-20-0164 (“Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population”).
- B. The Privacy Act of 1974 (5 U.S.C. 552a) “requires the safeguarding of individuals”, and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either individual’s name or some other identifier. This law also requires that such records in NCHS are to be protected from “uses other than those purposes for which they were collected.”

It is the responsibility of NCHS employees, including NCHS contract staff, to protect and preserve all SLAITS data from unauthorized persons and uses. All NCHS employees as well as all contract staff have received appropriate training, made a commitment to assure confidentiality, and have signed a “Nondisclosure Affidavit” every year. Protection of the confidentiality of records is a vital and essential element of the operation of NCHS, and it is understood that federal law demands that NCHS provide full protection at all times of the confidential data in its custody. Only authorized personnel are allowed access to confidential records and only when their work requires it. When confidential materials are moved between locations, records are maintained to ensure that there is no loss in transit and when confidential information is not in use, it is stored in secure conditions.

SLAITS is an ongoing data collection effort and all appropriate contractor employee confidentiality trainings and nondisclosure signatures are current and in effect.

NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees involved in SLAITS must sign. The contractor provides all safeguards mandated by Privacy Act and Confidentiality legislation to protect the confidentiality of the data.

The contractor’s data security procedures comply fully with security requirements delineated by the Office of the Chief Information Security Officer (OCISO) of CDC. SLAITS has undergone Certification and Accreditation and has been granted Authority to Operate.

- C. Having provided sufficient justifications as required by the Department of Health and Human Services (HHS) Policy for Protection of Human Research Subjects Code of

Federal Regulations (45 CFR 46), the NCHS Research Ethics Review Board has waived the requirement for written consent for the SLAITS telephone surveys. This research presents no more than minimal risk to participants, and involves no procedures for which written consent is normally required outside of the research context. By waiving the requirement for written documentation of consent, the rights and welfare of respondents are not impacted in any way. It is impractical and infeasible to collect written informed consent from respondents due to the telephone interview mode; additionally, this research could not be practicably carried out without this waiver. However, informed consent is obtained verbally. Information on the uses of the data are provided in the advance letter (Attachment B) and in the consent text read to all respondents (Attachment A).

D. Respondents are notified of the voluntary nature of the survey through both the Advance Letter (Attachment B) and in the consent text read to all respondents (Attachment A).

11. Justification for Sensitive Questions

The NS-DATA instrument includes a few questions that may be considered to be sensitive. They are about medication diversion and disciplinary actions

NS-DATA questions that may be considered sensitive include:

- To the best of your knowledge, has [child]'s ADHD medication ever been taken or used by someone else, including a family member?
- Has [child] ever been expelled or asked to not return to a childcare center, preschool, or school?

Very limited information is available on drug diversion as it relates to ADHD medication usage, and yet improper use of stimulant medication is found in the literature. There is a clear need to better understand medication use.

Minimizing sensitivity---SLAITS takes the following steps to create a context which minimizes sensitivity and makes clear to respondents the legitimate need for the information:

- (1) First, it is always possible to answer "I don't know" (I can't recall, I don't remember, or I never knew that) or "Refuse to answer" for any question. "Refused" or "don't know" response options are not read to respondents as explicit answer choices for every question, but interviewers are trained to accept "don't know" or "refuse to answer" for **any** question. When informed consent is obtained, respondents are informed that they can refuse to answer any question or end the interview at any time.
- (2) Advance letters (Attachment B) are used to make clear that the survey is sponsored by the U.S. Department of Health and Human Services, and that the information is put to important uses. The Advance letters, on NCHS letterhead, cite the SLAITS web site (<http://www.cdc.gov/nchs/slaits.htm>), and respondents who want to verify the sponsorship of the survey for themselves can call the toll-free number at the data collection contractor. The back of the advance letter answers the most frequently asked questions.

- (3) Only professional telephone interviewers are used and all data are collected by telephone, minimizing social desirability issues that can arise in face-to-face interviewing on sensitive topics.
- (4) The questionnaire is carefully crafted to lead smoothly from one topic to another. As new topics are introduced, brief transition text is used to move from topic to topic.

12. Estimates of Burden Hours and Costs

The table below (Table 1) illustrates projected burden for the survey.. The three-year SLAITS clearance package contained provisions for one main survey implementation per year. Therefore, the burden is accounted for in the original package.

NS-DATA cases have been pre-screened for NS-DATA eligibility by having previously completed the NSCH 2011-2012 interview. The first few completed interviews will be assessed to ensure that the questionnaire is operating as intended. Approximately 3,700 households will complete the NS-DATA, with interviews lasting approximately 30 minutes, for a total projected burden for the survey of 1850 hours. Skip patterns will ensure the smoothest possible progress through the interview. Parents and guardians of children who have been diagnosed with ADHD and TS will have a 50 minute interview. Approximately 50 children have both conditions, which given its rare occurrence does not affect the overall average burden per response.

Table 1. Burden estimate, NS-DATA

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Household members ¹	NS-DATA	3700	1	30/60	1850
	TOTAL PROJECTED BURDEN HOURS				1850

¹This is a pre-screened sample which includes eligible families identified through administration of the NSCH 2011-2012.

The burden for this study is 1850 burden hours. SLAITS is currently cleared for 194,675 burden hours over the course of the three-year clearance, so we are NOT requesting an increase in the number of burden hours.

Table 2. Hypothetical cost to respondents estimate, NS-DATA

Type of respondent	Form Name	Total Burden Hours	Respondent Wage Rate per Hour	Total Estimated Costs
Household members ¹	NS-DATA	1850	\$21.00	\$38,850

¹This is a pre-screened sample which includes eligible families identified through administration of the NSCH 2011-2012.

At an average wage rate of \$21.00 per hour and an average length of 30 minutes for the 3,700 respondents (including those who screen out of the survey), the average cost per respondent is \$10.50 for a total estimated cost of \$38,850 (Table 2). (Wage rate information is from the Bureau of Labor Statistics: <http://www.bls.gov/ncs/ocs/sp/nctb1344.pdf>). This estimated cost does not represent an out of pocket expense, but represents a monetary value attributed to the time spent doing the interview.

13. Estimates of other total annual cost burden to respondents or record-keepers

No capital or maintenance costs are involved.

14. Annualized cost to the Federal government

The cost for NCHS to conduct the NS-DATA (full survey implementation) is approximately \$1,200,000.00 (Table 3) and will be completed within one year (Table 4). The costs are supported by NCBDDD through an Interagency Agreement (IAA). NCBDDD funds are used to support contractor and NCHS staff salaries; survey planning, design, and development; training; coding; data collection, weighting and preliminary estimation; printing of survey materials; file release; and incentives used to address non-response. Details are shown below:

Table 3. Annualized cost, NS-DATA

Funding Source	Amount
NCBDDD (federal government)	\$1,200,000.00
Total Projected Cost	\$1,200,000.00

15. Explanation for program changes or adjustments

This is a genIC so there are no burden changes.

16. Plans for Tabulation and Publication and Project Time Schedule

The projected timeline is listed in Table 4. The data generated from the survey are critically important to NCBDDD. Based on prior experience and NCBDDD's NS-DATA analysis plan, products for the main survey will include research articles written for scientific journals,

government reports and a methodology report. Findings will be disseminated through traditional research venues such as conferences, peer-reviewed journals, and research posters. Findings are also disseminated through professional meetings of interest to academic researchers, survey methodologists, and policy makers; and professional reports. Study findings, publications, data files, and documentation will be available at no cost on the NCHS and NCBDDD websites. Published materials will be included in publicly accessible bibliographic databases such as Medline (available through the National Library of Medicine, www.nlm.nih.gov) and may be disseminated in the lay media by medical journalists. A separate detailed methodology report will be prepared by NCHS after the main survey is completed.

An announcement detailing the data file release will be disseminated by the CDC Office of Public Affairs through various listservs (including the SLAITS listserv with almost 1,000 subscribers around the world).

Table 4. Tentative projected schedule, NS-DATA.

Activity	Date
Conduct NS-DATA interviews	January – April 2014
Prepare methods report and file documentation	October 2014
Public Use File release	November 2014

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.